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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,297	08/24/2005	Jonas Angstrom	0933-0232PUS1	6676

2292 7590 12/09/2010  
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EXAMINER
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BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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12/09/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/518,297	<b>Applicant(s)</b> ANGSTROM ET AL.	
	<b>Examiner</b> LAYLA BLAND	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 76-92,94-104 and 106-115 is/are pending in the application.
- 4a) Of the above claim(s) 76-91 and 98-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 92,94-97,106-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

This Office Action is in response to Applicant's request for continued examination (RCE) filed September 20, 2010, and amendment and response to the Final Office Action (mailed March 18, 2010), filed September 20, 2010 wherein claims 110-115 are newly submitted.

Claims 76-92, 94-104, and 106-115 are pending in this application. Claims 76-91 and 98-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 5, 2007.

Claims 92, 94-97, and 106-115 are examined on the merits herein.

The following rejections of record are modified:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 92, 97, 106, and 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finke (CA 2394090, June 14, 2001, of record).

Finke teaches an oligosaccharide composition which approximates to human milk [see abstract]. Human milk oligosaccharides support the normal intestinal flora necessary for function of the gastrointestinal tract and repress pathogenic germs [page 1, lines 26-30] and prevent the adhesion of pathogenic germs and/or substances such as bacteria, toxins, and eukaryotic parasites, the first step of an infection being thereby prevented [page 2, lines 1-9]. Isolation of oligosaccharide fractions can be done using known separation methods [page 5, lines 21-22]. The oligosaccharide mixture can be used as prophylaxis against gastrointestinal infections or for treating of disorders caused by a faulty bacterial or viral colonization of the gastrointestinal tract [page 8, lines 1-13, and claim 8]. The oligosaccharide mixture should contain a neutral fraction

and an acidic fraction [page 4, lines 25-28]. Suitable acidic oligosaccharides include 2,3'-sialyl lactose (one elected species) [page 11, Example 4] and suitable neutral oligosaccharides include lacto-N-neo-tetraose (other elected species) [page 11, Example 5]. Finke teaches administration of the claimed oligosaccharides to the claimed patient population (those in need of treatment for gastrointestinal infection).

Although Finke teaches administration of a combination of an acidic and a neutral oligosaccharide and teaches the elected species as examples of acidic and neutral oligosaccharides, Finke does not teach an example wherein 2,3'-sialyl lactose and lacto-N-neo-tetraose are administered together. It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer 2,3'-sialyl lactose and lacto-N-neo-tetraose for treatment of disorders of the gastrointestinal tract. Finke teaches that oligosaccharides are useful for supporting normal intestinal flora and repressing pathogenic germs, and preventing adhesion of germs, and further teaches that the combination of an acidic and a neutral oligosaccharide is particularly effective. Thus, the skill artisan would administer a combination as taught by Finke. The skilled artisan would look to Finke for guidance as to which neutral and acidic oligosaccharides would be effective. Among specific acidic oligosaccharide species taught by Finke, there are 2,3'-sialyl lactose, 2,6'-sialyl lactose, 2,3'-N-glycolyl neuraminyllactose, and 2,6'-N-glycolyl neuraminyllactose [Example 4] and disialyl lactose [Example 5]. Among specific neutral oligosaccharide species taught by Finke, there are three isomeric galactosyl lactoses, fucosylized lactosamine and lactose units extended by N-acetyl galactosamine or N-acetyl glucosamine [Example 4], Lacto-N-neo-tetraose and lacto-N-

neo-hexaose [Example 5]. These represent a small number of specific, identified oligosaccharides from which the skilled artisan would choose.

### ***Response to Arguments***

Applicant argues that, based on Finke, the skilled artisan would have to blindly choose from all neutral and acidic oligosaccharides present in animal milks to arrive at the claimed invention. This argument is not persuasive because, although Finke teaches that a broad genus of oligosaccharides can be used, Finke exemplifies and identifies only a small number of discrete oligosaccharides. The skilled artisan would look to Finke's examples for guidance, and would not simply choose blindly from all possible oligosaccharides. Applicant's elected species are among the few which are specifically identified by Finke, so it would be obvious to choose those.

Claims 92, 94-96 and 106-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finke (CA 2394090, June 14, 2001, of record) in view of Zopf (Lancet Vol 347, April 13, 1996, pp. 1017-1021, of record), Pickering (Infection 21 (1993) No. 6, pp. 355-357, of record), Vanmaele et al. (WO 00/51644, September 8, 2000, PTO-1449 submitted December 17, 2004), Prieto et al. (US 6,083,934, July 4, 2000, of record), and Zopf et al. (US 5,883,079, March 16, 1999).

Finke teaches administration of an oligosaccharide mixture for treatment of gastrointestinal infection caused by bacterial or viral colonization of the intestinal tract, as set forth above. Finke does not teach specific pathogens or their effects.

Zopf (1996) teaches that bacteria for which oligosaccharides have been shown to be prophylactic or therapeutic *in vivo* or are effective antiadhesive agents include *Escherichia coli* and *Helicobacter pylori*, as well as *Salmonella typhimurum* and *Vibrio cholerae* [page 1017, Table]. It is noted that *Escherichia coli* and *Helicobacter pylori* are known to cause diarrhea, as mentioned in the instant specification (page 1).

Pickering teaches that human milk oligosaccharides are protective against *Campylobacter jejuni*, enteropathogenic *E. coli*, and enterotoxigenic *E. coli* [page 355, Table 1].

Vanmaele teaches that oligosaccharides comprising the sequence Gal  $\beta$  (1-4)GlcNAc (such as the elected species) reduce the virulence of enteropathogenic *E. coli* [page 15, last paragraph and page 16, Table 2]. Carbohydrate compounds may be used to treat EPEC infection [page 18, lines 17-18] and similar strategies might be effective in treating other pathogens [page 10, lines 7-10].

Prieto teaches a process of inhibiting bacterial infections caused by Bacteriodes, Clostridium, and *E. coli* by administration of a composition comprising Lacto-N-neo-Tetraose (LNnT) [see abstract].

Zopf (1999) teaches a method of inhibiting *H. pylori* infection or reinfection in a mammalian patient comprising administering NeuAc- $\alpha$ (2-3)-Gal- $\beta$ -(1-4)Glc [claim 7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer Finke's composition to a subject suffering from or at risk for bacterial infections such as those taught by Zopf, Pickering, Vanmaele, or Prieto. Finke teaches the treatment of bacterial gastrointestinal infections generally,

and the cited references teach particular bacteria which are known to be treatable using oligosaccharides, particularly the elected species and oligosaccharides comprising Gal  $\beta$  (1-4)GlcNAc . Thus, the skilled artisan could predict that the bacterial infections taught by the cited references could be treated using Finke's oligosaccharide composition.

### ***Response to Arguments***

Applicant's argument with respect to the breadth of Finke's disclosure was addressed above. Applicant's argument with respect to specific compounds and specific pathogens is moot in view of the new ground of rejection and the references cited above.

### ***Conclusion***

No claims are allowed.

This application contains claims 76-91 and 98-104, drawn to an invention nonelected with traverse in the reply filed on December 5, 2007. The previous office action set forth that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Applicant is again notified that cancellation of nonelected claims or other appropriate action is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Examiner, Art Unit 1623